UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,130	07/11/2003	Donald R. Owen	040219.03	2946

7590 12/15/2006

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, VA 22320

EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,130	OWEN ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *225-271* is/are pending in the application.

4a) Of the above claim(s) *225-227 and 236-243* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *228-235 and 244-271* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/03, 11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, Claims 228-235 and 244-271 (as amended) in the reply filed on 9/28/2006 is acknowledged. The traversal is on the ground(s) that search and examination of the entire application could be made without a serious burden because the subject matter of all claims is sufficiently related that a thorough search for the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. This is not found persuasive because the examiner has established that the groups of claims are distinct for the reasons already of record and has established that search of all the groups would be a burden as shown by their different classification and different fields of search required when examining the different groups of claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 225-227 and 236-243 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/28/2006.

Information Disclosure Statement

3. The information disclosure statements filed 7/11/2003 and 11/10/2005 have been considered and made of record.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 253, 265 and 266 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 253, 265 and 266, "said diagnostic device" lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 228, 230, 232, 233 and 235 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy (US 5,586,438).

With respect to claim 228, the reference of Fahy discloses a system for holding an organ that includes a portable housing (11) for holding the organ; an organ perfusion apparatus (256)

adapted to receive the portable housing; and a transporter (256) adapted to receive the portable housing. Note the reference discloses the use of two separate structures (256) for receiving the portable housing, a first structure for transporting the housing to an airport and a second structure for carrying the housing on an airplane (See column 14, liens 10-19). Either of the devices are capable of perfusion, transport and/or static storage of the organ without removal of the organ from the portable housing.

With respect to claim 230, the portable housing includes tubing and connection devices (See Figure 1).

With respect to claim 232, the portable housing is made of a transparent material (See column 3, line 67).

With respect to claim 233, the disclosed use of the device for transport to and on an airplane meets the claim limitations of claim 233.

With respect to claim 235, the organ is connected to tubing and connection devices (See Figures 1 and 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 231 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438).

The reference of Fahy has been discussed above.

Claim 231 differs by reciting that the portable housing (11) includes a handle.

In the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one having ordinary skill in the art to provide the housing of the primary reference with a handle so as to facilitate the removal of the housing from storage box (200).

12. Claims 229 and 234 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438) in view of Fahy et al.(WO 96/29865).

The reference of Fahy has been discussed above.

Claims 229 and 234 differ by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the system without removal of the organ from the housing would have been obvious for the known and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

13. Claims 244, 246-253, 255, 256, 258-263 and 265 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438) in view of Armstrong et al.(US 6,238,908).

The reference of Fahy has been discussed above.

With respect to claims 244 and 256, while the reference of Fahy discloses the use of a microprocessor for data tracking (See column 16, lines 6-12), the reference does not disclose that the portable housing includes transferable data regarding the housing and its contents.

The reference of Armstrong et al. discloses that it is known in the art to provide a portable culture device with a memory device for interfacing the portable device with a plurality of different system devices (See column 10, line 58, to column 11, line 7, and column 15, lines 27-50).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with transferable data regarding the housing and its contents as is conventional in the art for transferring stored data between different system devices that interface with the portable housing.

With respect to claims 246 and 258, the portable housing includes tubing and connection devices (See Figure 1 of Fahy).

Claim 247 differs by reciting that the portable housing (11) includes a handle.

In the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one having ordinary skill in the art to provide the housing of the primary reference with a handle so as to facilitate the removal of the housing from storage box (200).

With respect to claims 248 and 259, the reference of Armstrong et al. discloses the use of a tag device (206).

With respect to claims 249-252 and 260-263, the specific information recorded and transferred would have been well within the purview of one having ordinary skill in the art based merely on the intended use of the organ.

With respect to claims 253 and 265, the system devices when used as recited above would be capable of receiving the data from the housing.

With respect to claim 255, the bottom portion of the housing is liquid-tight and configured to collect medical fluid.

14. Claims 245 and 257 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438) in view of Armstrong et al.(US 6,238,908) taken further in view of Fahy et al.(WO 96/29865).

The combination of the references of Fahy and Armstrong et al. has been discussed above.

Claims 245 and 257 differ by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the

system without removal of the organ from the housing would have been obvious for the known and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

15. Claims 254 and 271 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438) in view of Armstrong et al.(US 6,238,908) taken further in view of Coble et al.(US 5,451,524).

The combination of the references of Fahy and Armstrong et al. has been discussed above.

Claims 254 and 271 differ by reciting that the system includes an image recording device.

The reference of Coble et al. discloses that it is known in the art to study or observe cultured or perfused organ tissue sample over time with a video camera (See column 9, lines 44-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to monitor the contents of the housing over time with an imaging device for the known and expected result of optically monitoring the condition of the organ over time.

16. Claims 264, and 266-270 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5,586,438) in view of Armstrong et al.(US 6,238,908) taken further in view of Schafer (US 6,300,875).

The combination of the references of Fahy and Armstrong et al. has been discussed above.

While the reference of Fahy discloses the transport of the housing by airplane from one point to another, the reference is silent with respect to computer tracking of the housing.

The reference of Schafer discloses that it is conventional in the art to track a portable package using a GPS system and networked computer system (See the abstract and Figure 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to track the organ housing using a system as disclosed by the reference of Schafer for the known and expected result of providing a means recognized in the art for tracking a portable package.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB